

**REMARKS**

The examiner is thanked for the very thorough and professional office action, and especially for providing a detailed response to our previously submitted arguments.

Pursuant to that office action, claims 4 and 13-15 have been cancelled and claims 18, 20 and 22 have been rewritten to more definitely set forth the invention and obviate the rejections. In particular, the format of these claims has been rewritten to clarify the process step involved in each of these method claims. In addition, new claims 23 and 24 are presented setting forth a method of preparing an external skin preparation. The present amendment is deemed not to introduce new matter. Claims 18, 20, 22, 23, and 24 are in the application.

Reconsideration is respectfully requested of the rejection of Claims 4, 13-15, 18, 20 and 22 under 35 U.S.C. 103(a) as being unpatentable over Lentini, et al. (WO 11/33803) and Katsuhiro (JP 01-165517) in view of Tanaka (USP 5,540,921).

**The Problem To Be Solved**

Applicants carried out an investigation to develop a method for reducing skin irritation of ultraviolet absorbent compositions containing octyl methoxycinnamate when blended with powders of titanium oxide and zinc oxide (Specification, page 2, lines 11-23).

**Applicants' Discovery Of The Problem**

The inventors found that octyl methoxycinnamate with skin irritant activity does not necessarily cause the irritation when it is at 10% or less in external skin preparations but causes the irritation when blended with the powders (emphasis ours). It is these powders which possibly

have an action to enhance the irritation of the skin by octyl methoxycinnamate (Specification, page 8, last seven lines).

To verify this fact, the inventors carried out the tests in Examples 1-4 and Comparative Examples 1 and 2 as shown in Table 1 on page 9 of the Specification. These tests confirmed, among other things, especially Comparative Examples 1 and 2, that the skin irritation of octyl methoxycinnamate is never exerted in case of no zinc oxide powder blended in, and that the co-presence of both the two triggers exerted skin irritation (Specification, page 11, lines 1-4).

From Table 1 and Table 2 in the specification herein, the following table was prepared.

	Comparative Example 1	Comparative Example 2	Example 2
Octyl methoxycinnamate	7.5	7.5	7.5
ZnO	20	--	20
Polyoxyethylene -glucoside	--	--	5%
Mean score (Irritation)	1.1	0.00	0.39

It can be seen from the above table that the combination of octyl methoxycinnamate with ZnO has unexpectedly strong skin irritation. (Comparative Example 1)

This table also shows that in an amount of 7.5% of octyl methoxycinnamate itself, skin irritation did not occur. (Comparative Example 2)

This table also shows that even in the presence of ZnO with octyl methoxycinnamate, blending in this sunscreen composition polyoxyethylene glycoside caused a significant reduction in skin irritation. (Example 2)

Finally, it can be seen from the tables 1 and 2 in the specification that other glycols do not have such effects (see comparative example 3 which used 1,3 butylene glycol 5% instead of polyoxyethylene glucoside of Example 2.)

It is respectfully submitted that Tables 1 and 2 in the Specification together with the above explanation clearly and unequivocally demonstrate the unexpected results achieved by the applicants' discovery of the problem and solution thereto which is now called for in the claims herein.

### **Applicants' Solution To The Problem**

The inventors discovered a method of reducing the skin irritation of ultraviolet absorbent compositions containing octyl methoxycinnamate with zinc oxide or hydrophobically treated zinc oxide by the step of blending in the composition a glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside, and mixtures thereof (Specification, page 3, last four lines, and page 4, lines 1-3).

### **The Issues Presented**

It is respectfully submitted that the facts in this case including the multi-reference rejection raises a number of important issues as follows:

1. Whether the discovery of the cause of a problem militates against a conclusion of obviousness, even though perhaps by hindsight the cause of the problem, once recognized, may suggest the solution?
2. Whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertained?

Applicants respectfully submit that the answer to the first issue is in the affirmative and is in the negative with respect to the second issue. Each of these issues will be discussed below.

### **The Law Concerning The First Issue**

Unobviousness can reside in the discovery of the cause of a problem, the solution of which employs a combination of old elements, *In re Spinnoble* 405 F2d 578, 160 USPQ 237 (CCPA 1969), even though by hindsight the cause of the problem, once recognized, may suggest the solution. *In re Linnert, et al.* 309 F2d 498, 135 USPQ 307 (CCPA 1962); *Trio Process Corp. v. L. Goldstein's Son's, Inc.* 461 F2d 66, 174 USPQ 129 (CA 3 1972); *In re Roberts, et al.* 470 F2d 1399, 176 USPQ 313 (CCPA 1973); *In re Peehs, et al.* 612 F2d 1287, 204 USPQ 835 (CCPA 1980); *In re Nomiya, et al.* 509 F2d 566, 184 USPQ 607 (CCPA 1975); and *Ex parte Campbell, et al.* 211 USPQ 575 (POBA 1980).

A reference which performs a step of a claimed process for a different purpose and does not recognize the problem solved in applicant's process does not render the process obvious. *Ex parte Wisdom, et al.* 184 USPQ 822. (POBA 1973).

### **Conclusion Regarding The First Issue**

The present inventors have presented in the Specification conclusive and unrefuted evidence that the main cause of irritation of sunscreen compositions containing octyl methoxycinnamate and zinc oxide powder may be the presence of the zinc oxide powder, and not necessarily the presence of octyl methoxycinnamate. Thus, the inventors herein discovered the

cause of the problem before moving on to find a solution thereto involving blending with the sunscreen composition a glucoside selected from the group consisting of polyoxyethylene methyl glucoside, polyoxypropylene methyl glucoside, and mixtures thereof.

None of the references of record in this case disclose the cause of the problem herein, i.e., the cause of irritation of sunscreen compositions containing octyl methoxycinnamate with zinc oxide powder. Although the prior art of record mentions that skin irritation can result from skin contact with octyl methoxycinnamate, there is no recognition of the problem that the presence of the zinc oxide powder may be primarily responsible for most of the skin irritation.

It is therefore very respectfully submitted that when the facts in this case are considered in light of the case law discussed above, the only reasonable conclusion is that unobviousness can reside in this case in the discovery of the cause of the problem which is nowhere recognized in any of the prior art of record. Consequently, it is respectfully urged that the examiner when weighing the facts in this case, and considering the case law, would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

#### **The Law Concerning The Second Issue**

Although obviousness does not require absolute predictability, at least some is required. *In re Whiton*, 402 F2d 1082 (CCPA 1970); and *In re Rinehart*, 531 F2d 1048, 189 USPQ 143 (CCPA 1976).

An invention is obvious if one of ordinary skill in the art would consider it logical to anticipate with a high degree of probability that a trial event would be successful. *In re Pantzer, et al.*, 341 F2d 121, 144 USPQ 415 (CCPA 1965). Same, a reasonable likelihood of success. *In*

*re Longi*, 759 F2d 887, 225 USPQ 645 (CAFC 1985). There is a lower level of predictability in chemical reactions and physiological activity than in mechanical and electrical environments. *In re Hogan, et al.* 559 F2d 595, 194 USPQ 527, 538 (CCPA 1977).

Because chemistry is often an empirical science, it is easy to characterize inventions in the field of chemistry as the result of “routine testing”. But even “routine testing” must be guided and directed by the mental concept of the inventor. “Routine experimentation” does not negate patentability. 35 U.S.C. 103, last sentence; *In re Fay, et al.* 347 F2d 597, 146 USPQ 47 (CCPA 1965).

Office personnel should consider all rebuttal evidence that is timely presented by the applicants when reevaluating any obviousness determination. Rebuttal evidence may include evidence of “secondary considerations” such as commercial success, long felt but unsolved needs [and] failure of others, and may also include evidence of unexpected results. Federal Register Notice, volume 72, October 10, 2007, at 57534.

Although the Supreme Court recently rejected the requirement that there must be some teaching, suggestion or motivation in the prior art that would have led one of ordinary skill in the art to modify the prior art references to arrive at the claimed invention, the Court nonetheless indicated that the lack of any teaching, suggestion or motivation in the prior art may still be considered as one factor in the overall determination of obviousness. *KSR International Co. v. Teleflex, Inc.*, 550 U.S. \_\_\_\_\_, 82 USPQ 2d 1385 (2007)

With respect to the second issue above, objective evidence of secondary considerations, such as unexpected results, are relevant to the issue of obviousness and must be considered in

every case in which they are present. See MPEP 2141 II. It is the duty of the Examiner to evaluate such evidence. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed.Cir., 1983); and *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed.Cir., 1986), cert. denied, 480 U.S. 947 (1987).

Proof of an unexpected improvement can rebut a prima facie case of obviousness. *In re Murch*, 464 F.2d 1051, 175 USPQ 89 (CCPA, 1972). No matter how strong the prima facie case of obviousness made out by the PTO, it must be weighed against any factors to the contrary brought out by the applicant in determining the validity of the conclusion of patentability unobviousness. *In re Lewis*, 443 F.2d 489, 170 USPQ 84 (CCPA, 1971). Therefore, facts established by rebuttal evidence must be evaluated along with the facts on which the conclusion was reached, not against the conclusion itself. *In re Lilly & Co.*, 902 F. 2d 943, 14 USPQ 2d, 1741 (CAFC, 1990).

### **Conclusion Regarding The Second Issue**

In considering the conclusions regarding the issue of obviousness, each of the three references in the examiner's combination rejection will be discussed separately as follows:

#### **The Lantini, et al. Patent**

Lantini, et al. disclose sunscreen compositions that feel better on the skin and are less irritating than typical sunscreens because the enhanced photo protection is not achieved by using greater quantities of the sunscreen agent (Page 1, lines 5-10). To achieve this result, Lantini, et al. disclose incorporating in the sunscreen composition a fluorinated polymer to increase the SPF of the sunscreen composition.

The teaching of Lantini, et al. is to reduce irritation of the skin by reducing the amount of organic sunscreen such as octyl methoxycinnamate (Page 6, line 10). Lantini, et al. disclose incorporating a fluoro-resin powder in the sunscreen formulations.

The Lantini, et al. patent, the examiner's primary or principal reference in the combination rejection, fails to recognize the cause of the irritation in sunscreen compositions containing octyl methoxycinnamate, with zinc oxide. Moreover, Lantini, et al. fail to recognize that sunscreen compositions containing octyl methoxycinnamate may not necessarily irritate the skin when no zinc oxide powder is present in the composition. That is, Lantini, et al. fail to recognize that it is the combination of the zinc oxide with octyl methoxycinnamate which causes irritation of the skin.

Further, the examiner has recognized during the prosecution of this case that Lantini, et al. fail to disclose the use of a glucoside in the sunscreen, as well as the hydrophobically treated zinc oxide now called for in the claims herein.

#### **The Katsuhiro Japanese Patent**

To cure the deficiencies of the examiner's primary patent of Lantini, et al., the examiner has cited the Katsuhiro reference as disclosing a cosmetic sunscreen composition comprising  $\text{TiO}_2$  and polyoxyethylene methylglucoside. The titanium dioxide particles have a particle size of 100-200 nm and from 3 to 10 % of the composition contains the polyoxyethylene methylglucoside (translated patent abstract of JP 01165517).

However, there is no disclosure in the Katsuhiro patent of the cause of the skin irritation of a sunscreen containing powdered zinc oxide and a glucoside such as polyoxyethylene



methylglucoside . Moreover, there is no recognition in Katsuhiro that it may be the presence of the zinc oxide powder which necessarily causes the skin irritation when such sunscreen compositions are applied to the skin. In addition, there is no disclosure or recognition in the Katsuhiro patent that adding a glucoside to a sunscreen composition containing zinc oxide powder and octyl methoxycinnamate would reduce the skin irritation caused by this sunscreen composition.

### **The Tanaka Patent**

The secondary reference of Tanaka discloses a solid oil-in-water cosmetic composition containing zinc oxide powder and the possible hydrophobic treatment thereof. However, like both the primary reference of Lantini, et al. and the secondary reference of Katsuhiro, Tanaka likewise fails to discover what causes the skin irritation of sunscreen compositions containing zinc oxide powder and octyl methoxycinnamate. Tanaka also fails to recognize that sunscreen compositions containing octyl methoxycinnamate without zinc oxide powder do not necessarily cause irritation of the skin. Thus, there is no recognition in Tanaka of the problem of the present invention, discovery of the cause of the problem, or a method of providing a solution thereto.

In addition, there is no teaching, suggestion or motivation in Tanaka for combining this reference with Lantini, et al. and Katsuhiro. Further, there is no disclosure in Tanaka of overcoming the skin irritation problem with sunscreen compositions containing octyl methoxycinnamate and zinc oxide powder by blending therein particular glucosides called for in the claims herein.

### **Discussion Of The Deficiencies Of The Examiner's References**

The examiner predicates the rejection on a combination of three references, none of which discover the problem in the prior art. That problem was the discovery that sunscreen compositions containing octyl methoxycinnamate with zinc oxide powder caused skin irritation but without the presence of zinc oxide powder do not necessarily cause skin irritation.

After discovery of the problem applicants unexpectedly discovered that this problem could be overcome by blending particular glucosides into the sunscreen composition containing zinc oxide powder and octyl methoxycinnamate.

It is understood from the rejection that the examiner considers that one of ordinary skill in the art would conclude that the present invention is obvious when all three of the cited references are considered by one of ordinary skill in the art. It is respectfully submitted that in order to reach such a conclusion, one of ordinary skill in the art would have to logically conclude with a high degree of probability that combining the references in the manner suggested by the examiner would be successful. See *In re Pantzer, et al.*, supra. However, it is respectfully urged that such a conclusion does not follow from the examiner's combination of references since none of these references even recognized or discovered the cause of the problem, much less a logical solution to that problem. It is respectfully submitted that it does not logically follow that one of ordinary skill in the art would combine these references without knowledge of the problem to be solved.

Moreover, it is difficult to conclude that with these references before them persons skilled in the art would logically anticipate with a high degree of probability that combining these references would be successful in solving the problem. How could those skilled in the art know how to solve the problem when they haven't discovered the cause of the problem?

Consequently, it is respectfully urged that it is a non sequitur to conclude that one skilled in the art would combine these references without knowledge of the problem to be solved. For this reason, it is respectfully urged that the unexpected results demonstrated in Tables 1 and 2 in the Specification and in the table above present evidence of unexpected results.

When the secondary indicia of non-obviousness such as unexpected results and commercial success are considered together with the fact that none of the references recognized or discovered the problem in the art to be solved, it is strongly urged that the overwhelming evidence of non-obviousness overcomes any prima facie case of obviousness made out by the examiner's combination of references. For these reasons, it is very respectfully submitted that the examiner would be justified in no longer maintaining the rejection. Withdrawal of the rejection is accordingly respectfully requested.

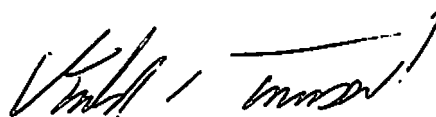
It is also respectfully submitted that those skilled in the art would not be motivated to combine Lantini, et al. which teaches reducing irritation by reducing the amount of sunscreen, with Katsuhiro which discloses using methylglucoside which is merely formulated as a humectant, the same as glycerine (Katsuhiro, page 3, lines 9-13). In summary, even though those skilled in the art would not be motivated to combine Lantini, et al. with Katsuhiro and Tanaka because none of these references suggest the unexpected technical problems of the present invention, the unexpected irritation caused by combining zinc oxide powder with octyl methoxycinnamate, and the unexpected benefit of adding methylglucoside to a sunscreen containing both zinc oxide and methoxycinnamate.

In view of the foregoing, it is respectfully submitted that the application is now in

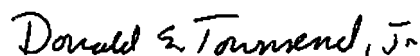
condition for allowance, and early action and allowance thereof is accordingly respectfully requested. In the event there is any reason why the application cannot be allowed at the present time, it is respectfully requested that the Examiner contact the undersigned at the number listed below to resolve any problems.

Respectfully submitted,

TOWNSEND & BANTA



Donald E. Townsend  
Reg. No. 22,069



Donald E. Townsend, Jr.  
Reg. No. 43,198

Date: February 15, 2010

TOWNSEND & BANTA  
Suite 900, South Building  
601 Pennsylvania Ave., N.W.  
Washington, D.C. 20004  
(202) 220-3124

**CUSTOMER NO. 27955**